REMARKS

Claims 34-37, 39, 41, 43, 44, and 71-73, as amended, remain herein. Claim 34 is amended to delete a word allegedly not supported by applicants' disclosure.

1. Claims 34-37, 39, 41, 43, 44 and 72 were rejected under 35 USC §112, paragraph 1, as allegedly failing to comply with the written description requirement, the Office Action alleging that the phrase "freestanding retention therein indefinitely" in claim 34 was new matter because the word "indefinitely" is allegedly not supported by applicants' disclosure.

Page 4, first paragraph of the Office Action agrees that the term "freestanding" is supported by applicants' disclosure, but the rejection remained based on the word "indefinitely." The word "indefinitely" has been deleted from independent claim 34, thereby mooting the rejection of that claim and all claims dependent thereon. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

2. Claims 34-37, 39, 41, 43, 44 and 71-73 were rejected under 35 USC §103(a) as allegedly obvious over Rashid British Patent 2,243,777 [GB '777] in view of Sioshansi U.S. Patent 6,030,333.

Rashid GB '777 discloses a device for sustained release of an active ingredient when the device is in contact with body fluids, which device includes a chamber containing the active ingredient and having an outlet therefrom; a capillary bore extending from the outlet for controlling the rate of release of the active ingredient from the chamber into body fluid, wherein the length and diameter of the bore are the controlling factors determining the release rate of the active ingredient into the body fluid. Rashid emphasizes the importance of the capillary bore stating that "the rate of release of active ingredient from the device is then controlled

predominantly by the length and diameter of the capillary bore, rather than by the rate of dissolution of the active ingredient or any other factor." (GB '777, page 2, lines 18-21). The Rashid device may have one or more outlets each provided with its own capillary bore. (GB '777, page 4, lines 17-19). If required, the open end of the capillary bore may be provided with a "copy" of sugar or gelatin which dissolves away on administration, or the bore may be filled with a soluble material which dissolves away on administration, thereby facilitating ingress of body fluids into the capillary tubing. Rashid discloses that the active ingredient within the device may be a medicament, contraceptive, or for prophylactic, diagnostic or nutritional use. (GB '777, page 5, last two lines).

The Office Action, page 7, first full paragraph, expressly admits that Rashid does not disclose that the active ingredients are "a radionuclide and a nucleic acid sequence, protein or polypeptide," as recited in applicants' claims.

The Office Action fails to acknowledge that applicants' independent claims 34 and 71 recite a drug delivery device consisting of only the recited elements which follow. As a matter of law, appellants' claims are limited to those recited elements, which do not include any capillary bore which is required by, and perhaps the most critical element of, the Rashid GB '777 device.

Sioshansi '333 discloses an implantable radiotherapy device. A traditional form of such device is illustrated in Sioshansi's Fig. 1 wherein a lead x-ray marker and Pd-103 plated graphite pellets are sealed within a titanium tube. Sioshansi '333 discloses a number of other devices which allegedly obviate the disadvantages of prior art radiotherapy seeds and encapsulated films, which employ a biocompatible radiotherapy delivery vehicle or template and at least one source

of radiation incorporated directly into a portion of the template to render that portion radioactive. A variety of shapes of such templates are disclosed.

Contrary to the impression given in the Office Action, pages 7-8, Sioshansi is not directed to implantable seeds, but to a template device for rendering seeds obsolete. The Office Action also points to Sioshansi's ability to deliver both radiation and non-radiation treatments together by applying on the surface of one or more portions of his templates therapeutic agents including biological agents such as proteins and growth factors. Such agents can be applied either directly onto the radioactive template, or onto the encapsulated coating 22 over the radioactive template, as desired for the specific application. See '333, col. 11, lines 53-63. The Office Action relies upon '333, col. 12, lines 57-61, which refer to radioisotopes such as low-energy gamma ray emitters. "Candidates might include, for example, ^{45}Ca, ^{123}Sn, ^{89}Sr, ^{32}P, ^{33}P, ^{103}Pd, and ^{125}I, although there other possibilities." ('333, col. 12, lines 60-62).

However, the Office Action fails to acknowledge that Sioshansi is not directed to interstitially implantable seeds, and particularly not to hollow seeds. Rather, Sioshansi is directed to templates which incorporate a source of radiation directly into the material of the template, thus forming a substantially sealed radiation source without the need for encapsulation of either the radiation source or the device. See '333, col. 4, lines 13-19. Furthermore, the Sioshansi device, as explained immediately above, is definitely not "for the controlled diffusion of the therapeutic agent which agent comprises a radionuclide and (1) a nucleic acid sequence, or (2) a protein or polypeptide," (as recited in applicants' claim 34), or "a radionuclide and (1) a viral vector comprising a nucleic acid sequence, or (2) a protein or polypeptide" (as recited in applicants' claim 71). Applicants' claimed drug delivery device is expressly constructed for

controlled diffusion of both a radionuclide and a nucleic acid sequence or vector comprising same. The prior art uniformly encapsulates and seals radioactive sources in any such implantable devices.

Rashid discloses a device that becomes unsealed by dissolution of plugs which initially block the required capillary bores thereof, but Rashid does not disclose diffusion release of radioactive therapeutic agent materials. Sioshansi discloses the use of radioactive therapeutic materials which are incorporated into the template material of his device, thus forming a substantially sealed radiation source without the need for further encapsulation of the radiation source or device. Applicants' claimed invention expressly provides controlled diffusion of the therapeutic agent which includes both a radionucleotide and a nucleic acid sequence, protein or polypeptide. Applicants' claimed invention is contrary to the fundamental and uniform teaching of the prior art that the radioactive material in implantable devices should be sealed or encapsulated. In applicants' claimed device the radionucleotide material is specifically intended to diffuse from the delivery device into the tissue or organ into which such device is implanted inter vivo.

Neither Rashid GB '777, nor Sioshansi '333 discloses all the elements of applicants' claimed invention. Furthermore, there is no disclosure or teaching in either Rashid or Sioshansi, or anything else in this record, that would have suggested combining any portions of their disclosures effectively to anticipate or suggest applicants' claimed invention to one of ordinary skill in this art. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

For all the foregoing reasons, all claims 34-37, 39, 41, 43, 44 and 71-73 are now proper in form and patentably distinguished over all grounds of rejection cited in the Office Action. Accordingly, allowance of all claims is respectfully requested.

The PTO is hereby authorized to charge/credit any fee deficiencies or overpayments to Deposit Account No. 19-4293. If further amendments would place this application in even better condition for issue, the Examiner is invited to call applicants' undersigned attorney at the number listed below.

Respectfully submitted,

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